Patent Foramen Ovale and Stroke: Closure by Further Randomized Trial Is Required!

Geoffrey A. Donnan, MD, FRACP; Stephen M. Davis, MD, FRACP

With the increasing use of transesophageal echocardiography as a diagnostic tool in ischemic stroke, where no obvious pathogenetic mechanism is evident, clinicians are more frequently faced with the finding of patent foramen ovale (PFO) as a possible or likely cause. For example, in a 45-year old woman with cryptogenic stroke and a large PFO, with spontaneous right-to-left shunt and atrial septal aneurysm (ASA), what should be the preferred management strategy? Further, what about optimal treatment in a similar case with PFO, without spontaneous shunting or atrial septal aneurysm, but a second clinical event and despite best medical therapy (whatever that is)?

Both our protagonists present reasonable arguments for percutaneous device closure (in some), clinical trials, or better definition of high-risk subsets before designing trials of device closure. There is clearly controversy concerning the precise criteria for high-risk PFO patients, with one major observational study suggesting that the presence of an associated aneurysm may significantly increase stroke risk.1 It should also be noted that the risk diminishes with age, so much so that it appears to be negligible in stroke-aged patients.2 Clearly, if one accepts causality, no optimal medical therapy has been identified and warfarin may be no better than aspirin.3 However, although it should be noted that this finding was based on a carefully planned substudy of the Warfarin-Aspirin Recurrent Stroke Study (WARSS), the mean age of the 203 patients with PFO was 58 years, an age where the overall risk was likely to have been low. Indeed, research in Melbourne suggests that PFO is not a risk factor for cerebral ischemia in those >50 years.2 What about the risks and benefits of percutaneous device closure? Like other interventional methods such as carotid artery stenting, there have been significant technological advances in device closure and recent reports indicate quite low complication rates.

What is our practice while awaiting level I evidence concerning medical therapy versus closure in patients with PFO? We would use standard antiplatelet therapy in a patient with a PFO alone, without spontaneous shunting and a first event. Conversely, for patients with a spontaneous right-to-left shunt and an associated ASA, we would consider device closure by an experienced interventionalist. Ideally, we would prefer to randomize patients in the latter group and other presumed high-risk patients to either device closure or medical therapy, but our centers are currently not involved in such a trial. Closure of this issue is required!

References


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